K121449

Cybernet Systems Co., Ltd.
Traditional 510(k) Premarket Submission
Direct Path

JUL 10 2012

Section 5 - 510(k) Summary for DirectPath

1. Sponsor Information

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JAPAN
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2. Applicant Information

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Contact: Diane Sudduth, Senior Consultant QA/RA

3. Date Prepared

April 17, 2012

4. Device Name

Trade/Proprietary Name:DirectPath
Common/Usual Name: DirectPath, Virtual Bronchoscopic Navigator
Classification Name: Computed tomography x-ray system
Classification Regulation: 892.1750
Product Code: JAK

5. Predicate Devices

KGT Inc. – Bf-NAVI K093810
VIDAS Diagnostics – VIDA Pulmonary Workstation 2 (PW2) K083227

6. **Device Description**

The DirectPath is a virtual bronchoscopic navigation software program designed to assist the physician during a bronchoscopic examination. The main purpose of the software is to generate a tracheobronchial tree using chest CT scan data in order to help the physician find an optimal bronchial route to the target region. The DirectPath software allows the physician to view a three-dimensional representation of the bronchial tree that displays virtual images of the inside surface of the bronchi. DirectPath is intended for use only as a guidance tool and does not make any medical diagnosis.

DirectPath is a Windows-based image software package. It is designed to capture pulmonary CT slice data and display results to assist the user in guiding endoscopic tools or catheters in the pulmonary tract. The software utilizes data from a CT scan to generate a three-dimensional image of the bronchus. DirectPath provides computed tomography viewing via Multi-Planar Reconstruction (MPR) to generate the three-dimensional image. DirectPath does not interface directly with any CT or data collection equipment; CT datasets are delivered via external storage devices (basically CD, DVD and USB Flash memory).

7. **Intended Use**

DirectPath is a virtual bronchoscopic navigation software program designed to assist the physician during bronchoscopic examination. The main purpose of the software is to generate a tracheobronchial tree using chest CT scan data in order to help the physician find an optimal bronchial route to the target region. The DirectPath software allows the physician to view a three-dimensional representation of the bronchial tree that displays virtual images of the inside surface of the bronchi. DirectPath is intended for use only as a guidance tool and does not make any medical diagnosis.

8. **Technological Characteristics and Substantial Equivalence**

DirectPath shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate device.

DirectPath is a Windows-based image software package. It is designed to load pulmonary CT slice data and create Multi-Planar Reconstruction (MPR) images to identify a target on a suspicious tumor area. DirectPath can display the pathway to and virtual bronchoscopic images of the target. The predicate device is similar in

design and function to DirectPath for the modes of operation and use and has the same intended use and indications for use as DirectPath.

9. **Safety and Effectiveness**

The device's software development, verification, and validation have been carried out in accordance with FDA guidelines. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The Device Hazard analysis was completed and risk control implemented to mitigate identified hazards. The testing results indicate that all the software specifications have met the acceptance criteria of each module and interaction of processes. The DirectPath device passed all testing and supports the claims of substantial equivalence and safe operation.

There was no clinical testing required to support the medical device as the indications for use are equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing. The verification and validation testing of the device was found to be acceptable and supports the claims of substantial equivalence.

10. **Conclusion**

By definition, a new device is substantially equivalent to a predicate device when the new device has the same intended use as the previously cleared predicate device and either (i) the same technological characteristics as the predicate, or (ii) if the new device has different technological characteristics, then those differences raise no new issues regarding the safety or effectiveness of the new device.

DirectPath device has the same or similar intended use and technological characteristics as the predicate device. The information provided in this submission supports the substantial equivalence to the predicate device and that the system is safe and effective for the users/operators.

In conclusion, the submitter believes that the DirectPath device, as designed and manufactured, is substantially equivalent to the referenced predicate device and does not introduce any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Cybernet System Co., Ltd.
% Ms. Diane Sudduth
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JUL 10 2012

Re: K121449
Trade/Device Name: DirectPath
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 17, 2012
Received: May 15, 2012

Dear Ms. Sudduth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4– Indications for Use Statement

510(k) Number (if known): Not Assigned

Device Name: DirectPath

Indications for use:

DirectPath is a virtual bronchoscopic navigation software program designed to assist the physician during bronchoscopic examination. The main purpose of the software is to generate a tracheobronchial tree using chest CT scan data in order to help the physician find an optimal bronchial route to the target region. The DirectPath software allows the physician to view a three-dimensional representation of the bronchial tree that displays virtual images of the inside surface of the bronchi. DirectPath is intended for use only as a guidance tool and does not make any medical diagnosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121449